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Minimizing Their Environmental Disposition while
Promoting Human Health
Part I: Rationale and Avenues toward a
Green Pharmacy

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Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition while Promoting Human Health

Part I: Rationale and Avenues toward a *Green Pharmacy*

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Pollution Prevention for Drugs in the Environment — Part I

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acronyms:
ADR: adverse drug reaction
CCL: Contaminant Candidate List
EEC: expected environmental concentration
EMA: The European Agency for the Evaluation of Medicinal Products
FDA: U.S. Food and Drug Administration
IOM: Institute of Medicine
MOA: mechanism of action
NSAID: non-steroidal anti-inflammatory
PEC: predicted environmental concentration
PPCPs: pharmaceuticals and personal care products
OTC: over the counter
TM/CAM: traditional, complementary, and alternative medicine
USP: United States Pharmacopeial Convention, Inc.
WHO: World Health Organization

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ABSTRACT

Since the 1980s, the occurrence of pharmaceuticals and personal care products (PPCPs) as trace environmental pollutants, originating primarily from consumer use and actions as opposed to manufacturer effluents, continues to become more firmly established. Although PPCPs have typically been identified in surface and ground waters, some are also undoubtedly associated with solid phases such as suspended particulates, sediments, and sewage sludges, despite their relatively high affinity for water. Often amenable to degradation, their continual introduction to waste-receiving waters results from their widespread, continuous, combined usage by individuals and domestic animals, imparting them with a "pseudo-persistence" in the environment. Little is known regarding the environmental or human health hazards that might be posed by chronic, sub-therapeutic levels of these bioactive substances or their transformation products. The continually growing, worldwide importance of freshwater resources, however, underscores the need for ensuring that any aggregate or cumulative impacts on (or from) water supplies be minimized.

Despite the paucity of effects data from long-term, simultaneous exposure at low doses to multiple xenobiotics (particularly non-target-organism exposure to PPCPs), a wide range of proactive actions could be implemented for reducing or minimizing the introduction of PPCPs to the environment. Most of these actions fall under what could be envisioned as a holistic stewardship program — overseen by the healthcare industry and consumers alike. Significantly, such a stewardship program would benefit not just the environment — additional, collateral benefits could automatically accrue, including the lessening of medication expense for the consumer and improving patient health and consumer safety.

This paper (the first of two parts describing the "green pharmacy") initially focuses on the background behind the imperative for an ecologically oriented stewardship program for PPCPs. It then presents a broad spectrum of possible source control/reduction actions, residing more under the control of the

health-care industry, that could minimize the disposition of PPCPs to the environment. The second part deals with those activities tied more closely to the end user (e.g., the patient) and the issues associated with drug disposal/recycling.

This two-part document attempts to cohesively capture for the first time the wide spectrum of actions available for minimizing the release of PPCPs to the environment. A major objective is to generate an active dialog or debate across the many disciplines that must become actively involved to design and implement a successful approach to life-cycle stewardship of PPCPs.